

Applicants:

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SPECIFICATION OF DIAGNOSTICS AND THERAPY OF EPSTEIN-BARR VIRUS

IN AUTOIMMUNE DISORDERS

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §1.56, Applicants cite the following publications, which are listed in the enclosed 21 pages of Form PTO-1449. Enclosed are copies of the International Search Reports for International Application Number PCT/US/91/00682 corresponding to U.S.S.N. 07/648,205 and PCT/US93/03484 corresponding to U.S.S.N. 07/867,819.

This application is a Continuation-In-Part of U.S.S.N. 07/160,604, filed on November 30, 1993, which is a Continuation-In-Part of 07/867,819, filed on April 13, 1992 which is a Continuation-In-Part of 07/648,205, which is a Continuation-In-Part of 07/472,947 now abandoned.

It is believed that no fee is required with this submission. However, if an additional fee is required, the Assistant Commissioner is authorized to charge Deposit Account No. 01-2507.

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INFORMATION DISCLOSURE STATEMENT

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Number	<u>Date</u>	<u>Name</u>	Class/Subclass
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exits. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their

U.S.S.N. 08/781,296 Filed: January 13, 1997

INFORMATION DISCLOSURE STATEMENT

claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patrea L. Pabst

Reg. No. 31,284

Dated: February 2, 1998

ARNALL GOLDEN & GREGORY 2800 One Atlantic Center 1201 West Peachtree Street Atlanta, Georgia 30309-3450 404/873-8794 404/873-8795 (fax)

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The "Received" stamp of the Patent Office imprinted hereon acknowledges the filing of:

Applicant: John B. Harley et al	•
Serial & Docket No.: 08/781,296	OMRF 161
Filed: January 13, 1997	
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Papers Submitted:

Information Disclosure Statement with Certificate of Mailing under 37 CFR 1.8(a) (in duplicate), 21 pages Form 1449A/PTO and referenced documents

Date: February 2, 1998

By: Patrea L. Pabst, Reg. No. 31,284

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Substitute for form 1449A/PTO	Com	plete if Known
/ SINFORMATION DISCLOSURE	Application Number	08/781,296
STATEMENT BY APPLICANT	Filing Date	January 13, 1997
	First Named Inventor	John B. Harley et al.
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Examiner's	Cite	US Patent Number	Document Kind Code ²	Name of Patentee or Applicant	Date of Cited Document	Pages, Columns, Lines, Where Relevant
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xaminer's Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T ²
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 08/781,296 January 13, 1997 Filing Date TATEMENT BY APPLICANT First Named Inventor John B. Harley et al. **Group Art Unit** Not yet assigned (use as many sheets as necessary) Examiner Name Not yet assigned 21 **OMRF 161 Attorney Docket Number** of

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Examiner's Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T²
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				Y APPLICANT	Filing Date	January 13, 1997	
	9 1998 4	.,			First Named Inventor	John B. Harley et al.	
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		OTHER ART NON PATENT LITERATURE DOCUMENTS	
xaminer's Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, cit and/or country where published	T²
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	·	Evans & Niederman, Epstein-Barr virus. In Viral Infections in Humans, 3rd ed. Evans, A.S. ed. pp 265-292 (Plenum, New York City 1989)	
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		Ferris and Donaldson, Veterinary Microbiology 18(3-4):243-258 (1988)	
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6	NPE INFORMATION DISCLOSURE	Application Number	08/781,296	
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	9 1998 =	First Named Inventor	John B. Harley et al.	
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		OTHER ART NON PATENT LITERATURE DOCUMENTS	
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		Fox, et al., "Detection of Epstein-Barr Virus-Associated Antigens and DNA in Salivary Gland Biopsies from Patients with Sjogren's Syndrome", <u>J. Immunol</u> ., 137:3162-3168 (1986)	
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STATEMENT BY APPLICANT	Filing Date	January 13, 1997
FEB 9 1998 2	First Named Inventor	John B. Harley et al.
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		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	
xaminer's Initials*	Cite	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	T²
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Substitute for form 1449A/PTO Complete if Known 08/781,296 **Application Number** INFORMATION DISCLOSURE January 13, 1997 Filing Date STATEMENT BY APPLICANT John B. Harley et al. First Named Inventor Not yet assigned **Group Art Unit** (use as many sheets as necessary) Not yet assigned Examiner Name **OMRF 161 Attorney Docket Number** 21 of

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		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	
xaminer's	Cite	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s),	
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_ FEB	9 1998 😩	First Named Inventor	John B. Harley et al.
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Initials*	No.1	publisher, cit and/or country where published	T ²
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		Morgan, <u>Vaccine,</u> 10:563-571 (1992)	
		Morgan, et al., <u>J. Med. Virol.</u> , 29:74-78 (1989)	
	<u></u>	Morland, et al., "Anti-idiotype and Immunosuppressant Treatment of Murine Lupus", Clin. Exp. Immunol., 83(1):126-132 (1991)	
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-		Newell & Stevens, "E.B. Virus Antibody in Systemic Lupus Erythematosus", <u>Lancet</u> , 1:652 (1971)	

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		Newkirk, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome", <u>Br. J. Rhuem.</u> , 33:317-322 (1994)			
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		Palfi, et al, "Purification of the Major UsnRNPs from Broad Bean Nuclear Extracts and Characterization of their Protein Constituents," Nucleic Acids Res. 17:1445-1458 (1989)			
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·	·	Phillips & Christian, "Myxovirus Antibody Increases in Human Connective Tissue Disease", Science, 168:982-4 (1970)			
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Substitute for form 1449A/PTO Complete if Known **INFORMATION DISCLOSURE Application Number** 08/781,296 Filing Date January 13, 1997 STATEMENT BY APPLICANT John B. Harley et al. First Named Inventor **Group Art Unit** Not yet assigned (use as many sheets as necessary) **Examiner Name** Not yet assigned of 21 Attorney Docket Number **OMRF 161**

		OTHER ART NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials†	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, cit and/or country where published	Т	
		Ravirajan & Staines, "Involvement in Lupus Disease of Idiotypes Id.F-423 and Id.IV-228 Defined, Respectively, Upon Foetal and Adul MRL/Mp-Ipr/lpr DNA-binding Monoclonal Autoantibodies" <u>Immunology</u> , 74:342-347 (1991)		
		Reichlin, et al., "Autoantibodies to the URNP Particles: Relationship to Clinical Diagnosis and Nephritis," Clin. Exp. Immunol. 83:286- 290 (1991)		
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		Rokeach, et al., "Molecular Cloning of a cDNA Encoding the Human Sm-D Autoantigen," <u>Proc. Natl. Acad. Sci. USA</u> 85:4832-36 (1988)		
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		Sabbatini, et al., "Autoantibodies from Patients with Systemic Lupus Erythematosus Bind a Shared Sequence of AmD and Epstein- Barr Virus-Encoded Nuclear Antigen EBNA I", <u>Eur. J. Immunol.</u> , 23:1146-1152 (1993) Saito, et al., "Detection of Epstein-Barr Virus DNA by Polymerase Chain Reaction in Blood and Tissue Biopsies from Patients with	
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		Scofield, et al., "Immunization with Short Peptides from the Sequence of the Systemic Lupus Erythematosus-Associated 60-kDa Ro Autoantigen Results in Anti-Ro Ribonucleoprotein Autoimmunity", <u>J. Immunology</u> , 4059-4066 (1996)	
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Substitute for form 1449A/PTO Complete if Known **INFORMATION DISCLOSURE Application Number** 08/781,296 Filing Date January 13, 1997 STATEMENT BY APPLICANT First Named Inventor John B. Harley et al. **Group Art Unit** Not yet assigned (use as many sheets as necessary) Examiner Name Not yet assigned 21 **Attorney Docket Number OMRF 161**

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,		Tigbe, Production of Human Rheumatoid Factors (RF) by SCID Mice Transplanted with Synovial Membrane Lymphocytes, presented at the Arthritis Foundation Fellows Conference, Amelia Island, Plantation, Florida, December 8-10 (1989)	
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		Toda, et al., Sjogren's syndrome (SS) and Epstein-Barr virus (EBV) reactivation. In Lacrimal Gland, Tear Film, and Dry Eye Syndrome D.A. Sullivan, ed. pp 647-650 (Plenum Press, New York 1994)	
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		Tsuzuka, et al., "Lupus Autoantibodies to Double-stranded DNA Cross-react with Ribosomal Protein S1 ¹ , ² " Arthritis & Rheumatism, 38(9):abstract 726 (1995)	

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		OTHER ART NON PATENT LITERATURE DOCUMENTS	
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		The Medical Letter on Drugs and Therapeutics 37(951):55-57 (June 23, 1995)	

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